DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
James I. McClammy
Marc J. Tobak
Gerard X. McCarthy

Counsel to the Debtors
and Debtors in Possession

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF FILING OF MONITOR'S REPORT

PLEASE TAKE NOTICE that Purdue Pharma L.P. hereby files on behalf of Thomas J. Vilsack, in his capacity as Monitor, the *Initial Monitor Report* attached as Exhibit A hereto.

Mr. Vilsack, as Monitor, prepared the *Initial Monitor Report* pursuant to the Voluntary Injunction entered as part of the *Second Amended Order Pursuant to 11 U.S.C. § 105(a) Granting Motion for a Preliminary Injunction*, entered on November 6, 2019 (the "**Preliminary**

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

Injunction Order"),[2] which requires that the Debtors retain a Monitor, and that the Monitor file a report no less than every 90 days regarding compliance by the Company with the terms of the Voluntary Injunction (the "**Monitor's Report**"). Purdue Pharma L.P. is filing the Initial Monitor's Report as a courtesy to the Monitor, who has not retained counsel in connection with these chapter 11 cases.

PLEASE TAKE FURTHER NOTICE that a copy of the Monitor's Report and any related papers may be obtained free of charge by visiting the website of Prime Clerk LLC at https://restructuring.primeclerk.com/purduepharma. You may also obtain copies of any pleadings by visiting the Court's website at https://www.nysb.uscourts.gov in accordance with the procedures and fees set forth therein.

Dated: May 20, 2020
New York, New York

/s/ Marc J. Tobak

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
James I. McClammy
Marc J. Tobak
Gerard X. McCarthy

Counsel to the Debtors
and Debtors in Possession

[2] Unless otherwise defined herein, each capitalized term shall have the meaning ascribed to such term in the Preliminary Injunction Order.

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	
	Chapter 11
PURDUE PHARMA L.P., *et al*.,	**Case No. 19-23649 (RDD)**
Debtor.[1]	**(Jointly Administered)**

INITIAL MONITOR REPORT

Comes now, Thomas J. Vilsack, as duly contracted Monitor for Purdue Pharma L.P. to report to the Court as follows:

EXECUTIVE SUMMARY

This Initial Monitor Report will include an outline of actions taken to date to determine compliance with the terms and conditions of the Voluntary Injunction, a general description of the documents and records reviewed, and a set of recommendations provided to Purdue Pharma L.P. and the company's responses thereto. Officials at Purdue Pharma L.P. have been responsive and cooperative by providing documents in a timely and complete fashion and by arranging for multiple interviews with key officials and providing more than 9,000 pages of documentation at my request. Based on what has been reviewed to date and subject to the recommendations contained herein Purdue Pharma and the Initial Covered Sackler Persons appear to be making a good faith effort to comply with the terms and conditions of the Voluntary Injunction.

1 The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

INJUNCTION

1. On November 6, 2019, the Bankruptcy Court entered a Preliminary Injunction order as part of the above entitled bankruptcy case. The Preliminary Injunction order included, as Appendix I, a Voluntary Injunction (Injunction) pursuant to which Purdue Pharma L.P., on its behalf and on behalf of its direct and indirect subsidiaries and general partner (collectively "Purdue Pharma"), agreed, in part, to retain a Monitor with the responsibility to report on compliance with the terms of the Injunction every 90 days. The Preliminary Injunction has been amended several times, but the Voluntary Injunction has remained the same each time. A copy of the currently operative Preliminary Injunction order, entered by the Bankruptcy Court on April 14, 2020, including the Injunction is attached hereto and made a part hereof as Exhibit One.

2. Under Part II Section A paragraph 1 a-h of the Injunction Purdue Pharma agreed to restrict the dissemination of information by Purdue Pharma or a Third Party on its behalf that was either likely or intended to influence prescribing practices of health care providers (HCPs) in favor of prescribing greater amounts, quantities, doses and/or strengths opioid products.

3. Under Part II Section B paragraph 1 of the Injunction Purdue Pharma agreed not to provide any financial incentive to its sales and marketing employees or take any disciplinary action against any of its sales and marketing employees that was directly based on or tied to the sales volume or quotas for opioid products unless otherwise permitted by the above entitled Bankruptcy Court.

4. Under Part II Section B paragraph 2 of the Injunction Purdue Pharma also agreed not to offer to pay any remuneration directly or through a Third Party to any person or entity for

the prescribing, sale, use, or distribution of opioid products other than the use of rebates or chargebacks.

5. Under Part II Section C paragraph 1 and 6 of the Injunction Purdue Pharma agreed not to provide any financial support or In-Kind support to any Third Party, medical society, or patient advocate group for the purpose of promoting opioid or opioid products including but not limited to the following: providing links to Third Party websites related to opioids or opioid products, knowingly using a Third Party to engage in activity prohibited by the Injunction, enabling or advocating for the appointment of a director, board member, employee, agent, or officer to serve in a similar capacity concurrently in any entity that promotes opioids, opioid products or opioid related treatment of pain or opioid related side effects except as authorized under the Part II Section C paragraphs 1 and 7 of the Injunction.

6. Under Part II Section D paragraph 1 of the Injunction Purdue Pharma agreed not directly or through a Third Party lobby for the enactment of any federal, state, or local legislation or for the promulgation of any rule or regulation that encourages or requires a health care provider to use opioids or sanctions a health care provider for the failure to prescribe or use opioids for the treatment of pain subject only to the limitations set forth in Part II paragraph D (4) of the Injunction.

7. Under Part II Section D paragraph 2 Purdue Pharma agreed not to directly or through a Third Party lobby against the enactment of any federal, state or local legislation or against the promulgation of any rule or regulation encouraging non-pharmacological or non-opioid pharmacologic therapy for the treatment of pain, the use of lowest possible dosages where appropriate of opioids or immediate release opioids, a limitation on an initial prescription of an opioid product, reasonable preconditions including testing before prescribing an opioid product,

the use of or payment for evidence based treatments for opioid use disorder, and the implementation of a proper disposal system subject only to the limitations set forth in Part II Section D paragraph 4 of the Injunction.

8. Under Part II Section D paragraph 3 of the Injunction Purdue Pharma agreed not to directly or through a Third Party lobby against the enactment of any federal, state or local legislation or against the promulgation of any rule or regulation that would limit the operation or use of PDMPs (Prescription Monitoring Program) including any requirement mandating the use of same before prescribing any opioid or opioid product.

9. Under Part II Section E of the Injunction Purdue Pharma agreed to abide by whatever decision is made by the Food and Drug Administration (FDA) on the pending Citizens Petition dated September 1, 2017 concerning a ban on high doses of prescription and transmucosal opioids exceeding 90 morphine milligram equivalents.

10. Under Part II Section F paragraph 1 of the Injunction Purdue Pharma agreed it would not directly or through a Third Party promote a savings card, voucher, coupons, or rebates programs to any health care provider for any opioid product or provide financial support to a Third Party to circumvent any such restriction. However, Purdue Pharma is authorized to provide savings cards, vouchers, coupons or rebate programs, including point-of-dispense programs, in response to requests or on its website under the Injunction.

11. Under Part II Section G paragraph 1 a-d of the Injunction Purdue Pharma agreed to operate an effective monitoring and reporting system to detect suspicious orders and possible diversion of opioids and opioid products by a direct customer or identify whether a downstream customer poses a material risk of diversion.

12. Under Part II Section G paragraph 2 of the Injunction Purdue Pharma agreed to promptly provide reasonable assistance to law enforcement agencies involved in investigations of potential diversions or suspicious circumstances involving Purdue Pharma opioid products.

13. Under Part II Section G paragraph 3 of the Injunction Purdue Pharma agreed that when and if one or more of the three largest pharmaceutical distributors establishes a system to aggregate transaction data involving the sale of opioid products and/or reports of suspicious orders Purdue Pharma would provide information into that system to the extent available and feasible, provided that the system is designed to use information provided by manufacturers of opioid products.

14. Under Part II Section G paragraph 4 of the Injunction Purdue Pharma agreed to refrain from acting as a distributor of opioid product (aside from rescue and treatment medications) directly to a retail pharmacy or health care provider that would require it to be registered as a distributor under the Controlled Substances Act unless otherwise required by local, state, or federal law.

15. Under Part II Section I of the Injunction members of the Sackler family as identified and described in Part I Section K, as Initial Covered Sackler Person, agreed not to be actively engaged in the opioid business in the United States other than by virtue of their ownership interest in Purdue Pharma and that they would individually or collectively take no action interfere with the Purdue Pharma's responsibilities and duties under the Injunction.

MONITOR AGREEMENT

16. On February 13, 2020 the undersigned and Purdue Pharma executed the Purdue Monitoring Agreement, attached hereto and made part hereof as Exhibit Two and began

immediately to take steps to comply with the monitor responsibilities as outlined in Part II Section H paragraphs 1-5 of the Injunction.

17. After the execution of the Monitoring Agreement in person or telephonic interviews were conducted of the following individuals whose titles were: Purdue Pharma President and CEO, Purdue Pharma Senior V.P., General Counsel and Corporate Secretary, Purdue Pharma Associate General Counsel, Purdue Pharma Chief Financial Officer, Purdue Pharma V.P. Business Operations, Purdue Pharma V.P. Research and Development, Purdue Pharma V.P. Medical Affairs, Purdue Pharma V.P. Chief Compliance Officer, Purdue Pharma V.P. Sales and Marketing, Purdue Pharma V.P. Chief Scientific Officer, Purdue Pharma Associate Director Ethics and Compliance, Purdue Pharma V.P. Federal Government Affairs, Purdue Pharma Executive Director, Head of Government Affairs, Rhodes Pharmaceuticals L.P. President, Rhodes Technologies President, Rhodes Pharmaceuticals L.P., V.P. Sales and Marketing, Rhodes Pharmaceuticals L.P. and Rhodes Technologies V.P., General Counsel, Rhodes Pharmaceuticals L.P. and Rhodes Technologies V.P., Chief Financial Officer, Purdue Pharma Director of Health Policy, Purdue Pharma Head of Market Access, Purdue Pharma Director Pharmacy Distribution Sales.

18. After the execution of the Monitoring Agreement, documents and records, listed in the document attached hereto and made a part hereof as Exhibit Three, were provided at an in person meeting at the corporate headquarters on February 13, 2020 and subsequently reviewed.

19. After the execution of the Monitoring Agreement documents and records, listed in the document attached hereto and made a part hereof as Exhibit Four, were produced on March 4, 2020 and March 8, 2020 and subsequently reviewed.

20. After the execution of the Monitoring Agreement documents and records, listed in the document attached hereto and made a part hereof as Exhibit Five, were produced on March 19, 2020 and March 20, 2020 and subsequently reviewed.

21. After the execution of the Monitoring Agreement documents and records, listed in the document attached hereto and made a part hereof as Exhibit Six, were produced on March 23, 2020 and subsequently reviewed.

22. After the execution of the Monitoring Agreement documents and records listed in the document attached hereto and made a part hereof as Exhibit Seven were produced on April 13, 2020 and subsequently reviewed.

23. After the execution of the Monitoring Agreement documents and records listed in the document attached hereto and made a part hereto as Exhibit Eight were produced on April 20, 21, 29, and 30, 2020 and subsequently reviewed. After the execution of the Monitoring Agreement documents and records listed in the document attached hereto and made a part hereof as Exhibit Nine were produced on May 11, 2020 and subsequently reviewed.

24. After the execution of the Monitoring Agreement websites and social media sites for Purdue Pharma and its related entities were examined and subsequently reviewed relating to opioids and opioid products including: PurduePharma.com, RhodesPharma.com, RxPatrol.com, Butrans.com, HysinglaER.com, Oxycontin.com, AskPurdueMedical.com, Purdue Twitter, and Purdue LinkedIn.

25. After the execution of the Monitoring Agreement websites and social media sites were examined for Purdue Pharma and its related entities relating to non-opioid products and non opioid related activities including: ImbriumThera.com, AdlonTherapeutics.com, AvrioHealth.com, GreenFieldsVentures.com, SlowMag.com, ColaceCapsules.com,Senokot.com,

KiwiBalance.com, Betadine.com, FirstAidMyths.com, AdhansiaXR.com, Aptensioxr.com, Colace Instagram, Betadine Instagram, Senokot Instagram, Senokot YouTube, Colace YouTube, Imbrium Twitter, Adlon Twitter, Imbrium LinkedIn, Adlon LinkedIn and Greenfield LinkedIn.

26. After the execution of the Monitoring Agreement websites, newsletters, magazines and journals for the American Pharmacists Association, American Society of Health System Pharmacists, America Pharmacist and National Community Pharmacy Association were reviewed.

27. After the execution of the Monitoring Agreement the following journals and publications were examined: Pharmacy Today, Journal of Pharmaceutical Sciences and Pharmacy Library.

28. After the execution of the Monitoring Agreement websites for McKesson Corp., AmerisourceBergen, Cardinal Health System, CuraScript Specialty Distribution, Morris and Dickerson, JM Smith, Rochester Drug Cooperative, NACDS, and Express Scripts were reviewed.

29. After the execution of the Monitoring Agreement outreach was conducted with the Unsecured Creditor Committee, Non Consenting States Group, and Consenting States Group.

30. After the execution of the Monitoring Agreement a letter from Senator Hassan to the FDA and response to concerns from Purdue Pharma and its related entities was reviewed.

31. After the execution of the Monitoring Agreement the FDA website and comments contained therein relating to the activity of the Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Product and Guideline were reviewed.

32. After the execution of the Monitoring Agreement outreach was conducted to lawyers at Debevoise, Milbank, and Joseph Hage Aaronson as legal representatives of the

Sackler family members as Initial Covered Sackler Persons as defined and discussed in Part I Section K and Part II Section I of the Injunction requesting certification of compliance with the terms and conditions of the Injunction applicable to the Initial Covered Sackler Family Persons.

33. After the execution of the Monitoring Agreement requests for additional information, clarifications of documents received, and identification of additional people to interview were made pursuant to emails sent to Purdue Pharma Associate General Counsel on February 17, 2020, on March 3,4,13,19 and 23, 2020, on April 7, 13, 15, 20, and 30 and on May 1, 2020.

PROMOTION PROHIBITED

34. Under the Injunction Part II Section A Purdue Pharma and its related entities are generally prohibited from promoting opioids or opioid products and cannot use a sales force to promote opioids and opioid products to health care professionals. In 2018 Purdue Pharma terminated its opioid and opioid products sales force.

35. During the period from December 2019 to the present Purdue Pharma used and continues to use a third-party contract sales force consisting of approximately 90 people for the purpose of promoting its non-opioid product, Adhansia XR®, which is authorized under the terms and conditions of the Injunction. The sales force has received enhanced Adhansia training regarding how to address questions unrelated to the product. If an Adhansia sales representative is asked a question about opioids, he or she must not answer the question posed, and instead must refer the query to Purdue's Medical Affairs Department.

36. During the period from December 2019 to the present Purdue Pharma has had and continues to have in-house and field based Market Access and Trade and Distribution teams that work with managed care organizations and pharmacy benefit managers in order to ensure

formulary coverage, as well as with wholesale customers to ensure that pharmacies maintain adequate supplies of branded opioid products are available to fill prescriptions being properly prescribed by health care providers.

37. For branded opioid products Purdue Pharma's Trade and Distribution team negotiates agreements with most of its wholesalers to distribute opioid products from their central distribution centers for products produced in the Purdue Pharma manufacturing facilities in North Carolina. More than 90% of the branded opioid products are sold to and distributed by three wholesale distributors.

38. The Trade and Distribution team at Purdue Pharma pays quarterly negotiated fees to its distributors per established agreements for which distributors agree to maintain certain minimum and maximum inventory levels and to provide updated inventory and sales data.

39. The sales data collected from wholesalers is provided through a third-party contractor which is used for multiple purposes including the monitoring of suspicious orders by the Ethics and Compliance department.

40. The fee gets paid quarterly as a credit against what the distributor pays for product. The primary purpose of this arrangement is to stabilize supply so that proper prescriptions get filled without delay. This arrangement does not appear to be designed to promote the use or sale of opioid products. However, during the next 90 days more information will be sought to understand fully all the ways the data is used to ensure that none of the reasons related to encouraging more prescribing or use of opioid products.

41. The Market Access team at Purdue Pharma focuses its efforts, in part, on overseeing the effort with managed care organizations and pharmacy benefit managers. Negotiations with managed care organizations and pharmacy benefit managers center on the

formulary status of the products being sold. Purdue Pharma pays a rebate to maintain the appropriate status as a preferred or non-preferred product for each of its products.

42. The benefit of being on a preferred status level in a formulary is that the co-pay paid by the ultimate customer is less than it would be if the drug were in a non-preferred status.

43. If Purdue Pharma engages in the purchase of data such purchases need to be lawful and at a fair market value to maintain compliance with the terms and conditions of the Injunction.

44. If Purdue Pharma engages in providing rebates, such rebates must be at arm's length and only with written prior approval.

45. Over the next 90 days effort will be made to determine if data purchases and concessions, if any, were made. If so, an examination will be into the reasons and circumstances for the purchases or concessions.

46. More inspection and investigation will be in this area to determine how best to avoid a circumstance where a rebate negotiation crosses a line between a good faith effort on the part of Purdue Pharma to ensure adequate product access as opposed to an unauthorized promotion of opioid products contrary to the terms and conditions of the Injunction.

47. In the training described in Paragraph 35 above the sales force is trained not to answer questions asked about opioid products. The sales force is not trained or authorized to detail opioid products, does not receive compensation based on prescriptions of opioids by HCPs they call on and operates as part of the non-opioid Adlon business of Purdue. They are trained not to answer any questions that cannot be answered with either approved Adhansia XR promotional materials or Adhansia XR's Full Prescribing Information. These questions, including any relating to opioids, should be directed to Purdue Pharma Medical Information.

Purdue structured the Adhansia call list based on existing prescribers of ADHD medications, and not based on health care professionals who have prescribed opioids in the past. However, overlap occurred with 1,338 health care providers.

48. **The recommendation has been made that the third-party sales force personnel involved with those overlapping health care providers execute on a semi-annual basis a certification that they have read the Injunction, have provided a list of any health care provider or customer called upon who may have inquired about opioid or opioid products, and acknowledge that each and every person on the list was only told to direct such inquiries to the Medical Affairs Department of Purdue Pharma. Purdue Pharma has agreed to this recommendation and has reached out to its third-party vendor to implement this recommendation.**

49. Prior to the Injunction going into effect Purdue Pharma and its related entities funded and engaged a third-party to assist with an ongoing post marketing study, required by the Food and Drug Administration (FDA). The study is titled "OxyContin post marketing study #4-*Changes in Fatal and Non-fatal Overdose among Patients Dispensed OxyContin after its Reformulation with Abuse-deterrent Properties – A Healthcare Database Analysis with Linkage to the National Death Index*-"which was required by the FDA as a post-marketing study of the safety of OxyContin®.

50. The study assessed changes in the rates of fatal and non-fatal overdose among people dispensed OxyContin or comparator opioids.

51. As part of that study data was being collected for the purpose of supporting the study.

52. In the normal course of business Purdue Pharma would at this point seek to publish the data in a scientific journal.

53. The study included an estimation of the change in the incidence rates of unintentional fatal or non-fatal overdose (OD) in patients prescribed OxyContin before and after its reformulation in August 2010.

54. The study also assessed changes in rates of overdose for OxyContin vs. individual primary and secondary comparator extended-release (ER) and immediate-release (IR) opioids around the time of OxyContin's reformulation.

55. **A recommendation is that if such data is published in a scientific journal and Purdue Pharma intends to link to the scientific journal on websites controlled by Purdue Pharma that a disclaimer be provided that includes reference to the risks associated with opioids and opioid products and the appropriate warning information contained in package inserts, prescribing information and medication guides. Purdue Pharma has agreed to this recommendation.**

56. On its current corporate website and social media sites Purdue Pharma indicates support for the following: wide dissemination of the medical guidance for patients who are prescribed opioid and opioid products, appropriate disposal for unused opioid products, the need for a patient's consent to be fully informed, the use of electronic prescribing and Prescription Monitoring Programs, the need for prescribers to have demonstrated competency in prescribing , the expanded availability of naloxone and medicated assisted treatment options for misuse, abuse and addiction, and the development of abuse deterrent formulations.

57. All of these representations appear to be in compliance with the terms and conditions of the Injunction. However, the Rhodes Pharmaceutical L.P. (Rhodes) website does not provide direct access to that supportive language.

58. **The recommendation is that the same cautionary language used on the Purdue Pharma website also should be used on the Rhodes website given it sells and distributes three branded opioid products and several generic opioid products. Purdue Pharma has agreed to this recommendation**.

59. On the websites and social media sites identified in Paragraph 24 above Purdue Pharma provides a wide range of information related to opioids and opioid products including the following: key attributes of medications, and any savings plan or other resources for specific medications.

60. On the Purdue Pharma websites and social media site there is language consistent with the product label, prescribing information, medication guidance, and package insert for each medication that outlines the risks of addiction, misuse and abuse, the direction to use non-opioid treatments first unless ineffective, proper disposal methods for unused product, encouragement to use Prescription Drug Monitoring Programs and the importance of prescribers having reviewed the Risk Evaluation and Mitigation Strategy (REMS) training recommendations before prescribing any opioid product.

61. These websites require the viewer to acknowledge the risks, warning, and precautions before allowing the viewer a detailed review of any other information available on the site. Unlike on the sites identified in Paragraph 25 above that promote a specific non-opioid product dedicated to the site, the sites identified in Paragraph 24 contain no language or links to any other information that could be construed as promotional.

62. However, the Purdue Pharma LinkedIn company page site is a site recommended for a change. While introducing the company to the 24,535 followers as of May 12, 2020, of the site reference is made to an employee base of 1,027 which does not reflect the decline in the number of employees since the Bankruptcy Court filing.

63. **A recommendation is made to update with current and accurate information on the Purdue Pharma LinkedIn site. Purdue Pharma has agreed to this recommendation.**

64. At the time of the filing of this Initial 90 Day Report the list of research investments involving opioids and opioid products, if any, for the period after January 1, 2019 to the present date is in draft form. Information on the website and documents provided by Purdue Pharma indicate that the only opioid related research that was funded in 2019 by Purdue Pharma relates either to the current 11 post marketing FDA required efforts that predated the Injunction or research related to a product called nalmefene which is a hydrochloride injection medication being tested to counteract an opioid overdose.

65. These research efforts would appear to be consistent with and in compliance with the Injunction requirements subject only to the recommendations made in Paragraphs 55 above relating to the publication of any data from research efforts. It is expected that when the 2020 reports are filed a similar conclusion will likely be reached.

66. There are no promotional materials for opioid or opioid products on Purdue Pharma's current website. Rhodes has on its website only a product catalogue that identifies generic and branded opioid products which are available for sale and distribution.

67. Purdue Pharma and its related entities have complied with the requirements of Title 21 Chapter I Subchapter D of the Food and Drug Administration of the Health and Human

Services Department's Rules and Regulations by providing package inserts for all opioid products sold by Purdue Pharma and its related entities. These package inserts contain specific language outlining the numerous risks and hierarchy of risks associated with the use of opioid products.

68. The package inserts used for these products also contain the "Boxed Warning" required by the Food and Drug Administration (FDA) that provides warnings, outlines a precaution to take, identifies possible adverse consequences, points out more at-risk populations, and alerts to the possibility of addiction, abuse and misuse.

69. These warnings, precautions, alerts and directions are also fully described in the Full Prescribing Information and Medication Guide that accompanies each product.

70. In the prescribing information there is additional information including the recommendation that anyone prescribing the opioid product complete the Risk Evaluation and Mitigation Strategy (REMS) training.

71. REMS training assures that each prescriber understands what opioids are, the risks associated with the use of opioids, the importance of proper dosage, the activities to avoid with the use of opioid products, the significance of the medication guide for patients, telltale signs of possible misuse and the importance of naloxone availability.

72. The Medication Guide designed for patients to read goes into detail about the warnings and risks associated with opioids and opioid products.

73. Labels for the opioid products also contain language to alert patients and prescribers to risks and the need to review the medication guide.

74. All of these materials and the messages contained therein appear compliant with the ban against promotions in the Injunction.

75. There is no evidence on social media for Purdue Pharma or any of its related entities of any promotion of opioids or opioid products.

76. Recent twitter postings on the Purdue Pharma Website discuss the importance of having naloxone available to save a life if and when an overdose situation arises.

77. On the Perspectives page of the Purdue Pharma website the only items appropriately highlighted are the need for reduced reliance on opioid products and how to handle addiction, misuse or abuse.

78. Based on a review of social media and other media outlets outlined in Paragraphs 24 and 25 above Purdue Pharma does not currently promote the use of opioids or opioid products through the use of traditional or social media advertising, social media optimization techniques or links to other sites promoting opioids or opioid products.

79. The first twenty entries that surface when Purdue Pharma is searched on the internet deal with the Bankruptcy case, the settlement of claims or opioid addiction, misuse or abuse.

80. The filed reports from Purdue Pharma and Rhodes reflecting compliance with the federal Sunshine Act and with state expenditure reports required by Massachusetts, California, Connecticut, Vermont, New York, and Nevada were for expenditures in 2018 and involved payments made in conjunction with OxyContin, Butrans® and Hysingla®. All of these expenses were paid long before the Injunction was in force and effect.

81. In addition, a draft of the 2019 federal Sunshine Act for Purdue Pharma and Rhodes was also provided with the understanding that the reports may change before filing.

82. There were reported expenses on the 2019 reports paid after the effective date of the Injunction related to opioid products; however, those expenses appear to be limited only to the continued work associated with the FDA required post marketing studies.

83. As such those expenses would not constitute promotion of opioid products under the terms and conditions of the Injunction. Request has been made for receipt of these reports on an ongoing basis when they are filed with the respective departments and jurisdictions to ensure compliance continues.

84. Purdue Pharma is not precluded from providing comment or input into the regulatory proceedings of the FDA, but up to the filing of this report officials at Purdue Pharma have not provided any comment on the following matters pending before the FDA: the Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee (Docket Number FDA -2019-N-5611) - involving tramadol, celecoxib, and extended release oral tablet formulation of oxycodone submitted by Intellipharmaeceutics Corp.; (Docket FDA-2019-N-5552) - new drug application for oxycodegol.

85. Purdue Pharma did provide comment, prior to the Injunction, in the FDA Docket 2017-P 5296 proceeding which is a Citizens' Petition to limit high dosage opioid products. However, Purdue Pharma took no position on the Citizens' Petition but raised questions for the FDA to consider as it proceeds to decide on the merits of the Citizens' Petition.

86. No person or official on behalf of a Purdue Pharma or its related entities has provided comment or input on any of the following items pending at the FDA that might directly or indirectly be considered a promotion of opioids or opioid products: Registration and Registration Fees: Controlled Substance and List 1 Chemical (DEA- 2020-0007-0001 recovering

costs of diversion efforts through fee increases);Proposed Collection; Comment Request; Health Care Providers' Understanding of Opioid Analgesic Abuse Deterrent Formulations (FDA-2019-N-5973-0001 providing information on understanding and perception of abuse deterrent formulations); Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program and Programs of All Inclusive Care for the Elderly (CMS-2020-0010-0002 compliance with Bipartisan Budget Act of 2018, the Substance Use -Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, and 21st Century Cures Act); Request for Information on Vaping Products Associated with Lung Injuries (FDA - 2020-N- 0597-0001 use of vaping products associated with recent lung injuries);Registration Requirements for Narcotic Treatment Programs with Mobile Components (DEA-2020-0005-0001 operation of mobile components to dispense narcotic drugs/detoxification treatments at remote locations); Draft Infection Control Guideline FRN 02.26.2020 (CDC - 2020- 0011-0001 occupational infection prevention and control); Developing a Workplace Supported Recovery Program: A Strategy for Assisting Workers and Employers with the Nation's Opioid and Substance Use Disorder Epidemics; Request for Information (CDC-2020-0025-0001 NIOSH plan to develop research on Workplace Supported Recovery); Distribution of Traceable Opioid Material (TOM) Kits across U.S. Laboratories 2020-04083 (CDC -2020 0025-0001 kit access); and Delta Impact Cooperative Agreement Evaluation Data Collection Instruments 2020-04082. (CDC -2020-0023-0001).

87. During 2019 Purdue Pharma did not have a sales force or marketing team for its branded opioid products so no money was spent on such a sales force or marketing team. Of the entire sales and marketing budget for 2019 only approximately 7% was spent on branded opioid

products. Of that 7% nearly 85% was spent on acquisition of data and the remaining 15% was spent primarily for storing and securing that data.

88. The balance of the sales and marketing budget for the branded opioid products was for website maintenance, postage, data transition and savings card expense. None of these investments appears to be used to promote opioid product sales.

89. Prior to the Bankruptcy proceeding, based on Drug Enforcement Agency (DEA) records OxyContin had a market share of approximately 4% of opioid prescriptions in the United States while today its prescription market share in the United States has declined to approximately 1.3% based on data provided by a third-party vendor.

90. According to financial records covering calendar year 2019 provided by Purdue Pharma sales on OxyContin declined by approximately 20% from sales in 2018 and by nearly 60% from sales in 2015.

91. According to financial records covering calendar year 2019 provided by Purdue Pharma sales of Butrans declined by approximately 45% from sales in 2018 and by nearly 50% from sales in 2017.

92. According to financial records covering calendar year 2019 provided by Purdue Pharma sales of Hysingla declined by approximately 22% from sales in 2018 and by nearly 30% from sales in 2017.

BONUS, SALARY AND INCENTIVES

93. In 2019 bonus and financial incentives for Purdue Pharma was based on a company scorecard identifying three factors to be used to determine, if a bonus should be paid out: value creation (30%), efficiency and process optimization (60%), and people and culture (10%).

94. To the extent the bonuses and financial incentives were based on efficiency and process optimization Purdue Pharma established a process of rewarding staff based on sales of products raising potential compliance concerns under the Injunction Part II Section H.

95. However, for 2020 the scorecard criteria was significantly changed. The basic three factors of value creation, efficiency and process optimization and people and culture remained the same. Purdue's branded business operating profit remains a factor of the innovation and efficiency pillar of the 2020 scorecard.

96. Instead, the company in the future would reward behavior that promoted an entrepreneurial mindset and advanced sales of only non opioid products. As a result the 2020 approach will no longer reward staff based on volume of opioid sales. If implemented as designed the current scorecard will be consistent with the Injunction provisions in Part II Section H.

97. In 2019 the Purdue Pharma had a different compensation model than described in Paragraph 93 above for its Market Access Team. The Market Access Team's Compensation System of Incentives for the 6 employees involved in sales to Managed Care Organizations and Pharmacy Benefit Managers identified two factors to consider in determining staff compensation: individual performance and corporate performance.

98. The individual performance element was based on an individual's performance of the "Top 10 Behaviors Based on Our Values" which do not appear directly related to product sales volumes or profits.

99. The corporate performance element was divided into two elements: corporate performance tied to the annual corporate objectives and product performance of the non-opioid product Adhansia XR.

100. In the documents and information requested no revision appears to have been made to the plan.

101. **If that system and those factors remain in place a recommendation would be to state and clarify that in the corporate performance element neither top-line opioid product sales or volume specifically will be used as a factor in calculating salaries or bonus.**

GRANTS AND IN KIND SUPPORT

102. Under the Injunction Part II Section C Purdue Pharma and its related entities are prohibited from providing financial support or in kind support, such as grants, to any third party for the purposes of promoting opioid or opioid products.

103. Purdue Pharma is not prevented under the Injunction from supporting efforts to combat opioid misuse, abuse and addiction.

104. For any grant to be made now by Purdue Pharma the process requires a review by a multi-disciplinary committee, including the law department and the Ethics and Compliance department, not connected to the sales and marketing departments. Contributions requested by a customer cannot be approved.

105. From November 26, 2019 to February 22, 2020 Purdue Pharma awarded grants to a variety of programs that involved either treatment or prevention of opioid misuse or abuse. Such grants would appear to be in compliance with Part II Section C of the Injunction.

106. An example of the type of grants recently approved was to EVERFI in 6 states connected to Purdue Pharma and its related entities to help fund training materials and a health and wellness curriculum for K-12 students and teachers.

THIRD PARTY PAYMENTS

107. Under the Injunction Part II Section B Purdue Pharma is prohibited from paying any remuneration directly or through a third party for the promotion of the sale, prescribing, use or distribution of opioids and opioid products.

108. Under the Injunction Part II Section C Purdue Pharma and its related entities are prohibited from offering or paying any remuneration to any third party to promote the prescribing, using, distributing, or selling opioids or opioid products.

109. A review of the state audit reports from California, Connecticut, Nevada, Vermont, and Massachusetts and the Federal Spend Reports for Purdue Pharma for 2018 reflects that no payments that would have violated the Injunction had it been in place in 2018.

110. The records for the first two months of 2019 were also reviewed and are in compliance with the Injunction and applicable Federal law.

SAVINGS PROGRAM

111. Under the Injunction Part II Section F Purdue Pharma is banned from promoting broadly defined prescription savings programs but allowed to have such plans and to respond to inquiries about available plans.

112. A review of company records indicated that Purdue Pharma and its related entities discontinued a savings plan for Butrans opioid products because a generic less expensive product became available.

113. However, through a third-party vendor Purdue Pharma still offers savings plans for its OxyContin and Hysingla products.

114. For both the OxyContin and Hysingla savings plans there are conditions and restrictions that are communicated on the company websites. The savings card information available for both products includes the "boxed warning" required for the products by the FDA. The savings card information available for both products through the company websites makes reference to the package insert, medication guide, and prescribing information for the products that sets forth a variety of warnings concerning the products and limitations on when and for what conditions the products should be used.

115. The savings card information for both products prevents the savings card from being used for customers paying cash or for those patients covered by Medicare or Medicaid programs.

116. The savings card information for OxyContin can only be used once every two weeks and is limited to a $70 savings and for Hysingla ER the benefits amount to $170 only after the customer has paid $25.

117. The offering of only the two savings plans under the current terms and conditions outlined appears to be in compliance with the Injunction.

SUSPICIOUS ORDER MONITORING

118. Under the Injunction Part II Section G Purdue Pharma and its related entities is required to operate an effective monitoring and reporting system that reasonably analyzes collected direct customer data and available downstream customer data to identify suspicious orders as defined in the Injunction Part I Section Q.

119. The company charged the Ethics and Compliance Department with operating the suspicious order monitoring program and directed the Associate Director of Ethics and

Compliance to lead that effort with backup assistance provided by three additional Purdue employees.

120. The Associate Director of Ethics and Compliance has held this role since March 2019. From 2012 to 2018, she was an Associate Director of the Law Enforcement Liaison and Education program with Purdue Pharma's Corporate Security Department.

121. She is a veteran law enforcement officer having served 15 years in the state of Georgia. Her last post prior to working for Purdue Pharma was as the Principal Agent for the Georgia State Medical Board. She served as the Georgia Chapter President of the National Association of Drug Diversion Investigators (2003-2020).

122. Purdue Pharma has adopted a Standard Operating Procedure (SOP) for identifying suspicious orders of existing customers. The SOPs (as well as other non-opioid controlled substances) requires a quarterly review of chargeback data for covered opioids and opioid products, continuous reviews of orders, and a process for additional review when an order or customer is flagged.

123. In addition, as of November 2019 Purdue Pharma required and will require its customers to complete an annual Wholesaler Due Diligence Questionnaire.

124. The questionnaire in part is designed to provide information on the customer's own suspicious order monitoring program. The customer is asked whether its program is homegrown or third-party vendor provided, the extent of any Federal Drug Enforcement Agency (DEA) review of the system, the number of orders reported to the DEA for further investigation, and action taken when an order is found to be suspicious.

125. The questionnaire asks whether a customer uses a Prescription Monitoring Program (PMP) to track patients seeking to fill a prescription at multiple pharmacies or seeking

to obtain prescriptions from multiple providers during a particular period of time. The specifics of Prescription Monitoring Programs vary by state, and state laws and regulations typically limit access to Prescription Monitoring Program data. The questionnaire also asks if customers review information on top prescribers for each customer and verify those prescribers through due diligence.

126. Purdue Pharma's customers and its customers' customers take a variety of approaches in designing their SOMs programs, as reflected in the questionnaire responses. They also deem varying numbers of orders to be suspicious under their suspicious order monitoring programs.

127. A number of Purdue Pharma's customers provided questionnaire responses that were incomplete, unsigned, unresponsive, or lacked accompanying documentation.

128. Examples include the following Wholesale Distributor Questionnaires: one distributor refused initially in its questionnaire to provide any information on its suspicious order monitoring system claiming it was proprietary; one distributor submitted an unsigned questionnaire; one distributor had not had its homegrown system reviewed by the DEA since 2007 based on its submission; one distributor clearly copied its questionnaire from another wholesale distributor raising serious questions about the truthfulness of the responses ; one distributor questionnaire indicated their suspicious order monitoring program was still being worked on and that no further report would be forthcoming until the summer of 2020; one distributor reported it had a "manual" system which had not been reviewed by the DEA; one distributor questionnaire made reference to an attachment explaining their suspicious order monitoring system that was not in fact attached; and one distributor questionnaire suggested it

was a pharmacy and did not need a suspicious order monitoring system. In most of the aforementioned examples no follow up occurred at a Purdue Pharma.

129. The Associate Director of Ethics and Compliance started working for Purdue Pharma and its related entities in 2019 and began a series of visits to some of the wholesale customers.

130. Her visits involve an inspection of security systems on the site and interviews with key staff involved in managing the storage of product and identifying suspicious orders.

131. The notes of these visits reflect discussion of the storage of product, but do not provide documentation or discussion that might have occurred regarding the customers' suspicious order monitoring efforts.

132. None of the visits in 2019 were to facilities of the largest distributors; however, some visits did occur in 2018.

133. The suspicious order monitoring system used at Purdue Pharma and its related entities relies on two factors: (1) an algorithm that identifies orders of unusual size, pattern and/or frequency and (2) manual thresholds that are established for each customer. Either or both these factors can identify an order that requires additional review.

134. The system relies on the use of an algorithm generated by third party vendor. It is based in part on national sales data. It uses a scoring system that takes into consideration a comparison of the order to a series of thresholds involving historic orders from the customer and from the industry. The cumulative score determines if the order is initially flagged.

135. The system seeks to identify orders of unusual size, unusual frequency, or those deviating from normal purchasing patterns which is consistent with DEA guidance.

136. If an order is flagged under the SOP, the order is reviewed and contact is made by email or by phone with the customer to determine if there is a reasonable explanation for the order. If there is not a satisfactory answer the order is rejected and the DEA is contacted.

137. In 2019 Purdue Pharma and its related entities received 16,220 orders of which 2461 orders were flagged and 10 were reported to DEA.

138. In the first two months of 2020 Purdue Pharma and its related entities 2084 orders were received with 340 orders being flagged and 10 orders reported to DEA.

139. Under the SOP there is not a limit set on orders reported to the DEA before additional steps are taken to investigate the reasons for multiple reports or before a business relationship is terminated.

140. In addition, in reviewing the Wholesaler Due Diligence Reports a question arises whether or not there is adequate staff to review and to follow up on any issues identified from the questionnaires such as those outlined in paragraph 128 above.

141. Some of Purdue Pharma's customers have homegrown suspicious order monitoring systems. Little detail is provided for some of those systems and in some cases, customers refused to provide detail about their system. In addition, some of these customers have not had the DEA review the effectiveness of the system.

142. Purdue Pharma's records reviewed to date reflect that at least one customer does not access a PMP system to check if their customer is patients are getting multiple prescriptions filled raising further concerns about monitoring efforts. It is unclear from the records reviewed whether this is due to state law restrictions on access to PMP data or if it is due to some other factor.

143. **Purdue Pharma is making an effort to monitor for suspicious orders. However, several steps could possibly strengthen the current system. An expert with experience as former Chief of Staff at DEA, Jodi Avergun, has been hired to review in detail the current system and to determine what, if any, recommendations could be made to strengthen it. The following may be areas to be examined: hiring additional staff or contracting with a third party to enable a more thorough review and follow up of the annual Wholesale Due Diligence Questionnaires, to allow for a more in-depth review of "homegrown" suspicious order monitoring systems, and to conduct more site visits that should be prioritized based on volume of activity and numbers of suspicious orders flagged.**

144. **In addition, her review could include a recommendation to amend the SOPs setting forth under what conditions, if any, future orders should be stopped or curtailed if monitoring identifies a pattern of repeated suspicious orders from a wholesaler, a response to the annual questionnaire raises concerns of an unreasonable risk of diversion of opioid product, and/or a site visit leads to a concern that an unreasonable risk of diversion or theft of opioid product exists.**

LOBBYING

145. Under the Injunction Part II Section D Purdue Pharma agreed to certain restrictions related to lobbying. At the federal level Purdue Pharma has a one person government affairs department that according to former V.P. of Federal Governmental Affairs, only monitors Congressional activity that may be relevant to Purdue Pharma or the pharmaceutical industry generally.

146. Assisting former V.P. of Federal Government Affairs in monitoring efforts was Director of Health Policy at Purdue Pharma, who is assuming the role performed by former V.P.

of Federal Government Affairs with reference to the monitoring of federal government activities following his retirement.

147. Former V.P. of Federal Government Affairs represented that Purdue Pharma and its related entities conducts no federal executive branch agency lobbying. However, he did review on a regular basis the Federal Register and other subscription services that may report on the DEA, the Food and Drug Administration and the Centers for Medicare and Medicaid.

148. In the most recent federal lobbying disclosure former V.P. of Federal Government Affairs on behalf of Purdue Pharma represented in the fourth quarter of 2019 the company spent $200,000 on lobbying activities on substance abuse and addiction in the health care and alcohol and drug general areas which appears consistent with the Injunction.

149. Purdue Pharma and its related entities contracted with a lobbying firm during 2019.

150. In its fourth quarter 2019 federal lobbying disclosure form the lobbying firm notified the government that on behalf of Purdue Pharma the consulting group had monitored activities related to drug abuse, misuse and prevention efforts.

151. Former V.P. of Federal Government Affairs provided information that law firms have been hired for monitor activities as well.

152. One firm does not appear to have lobbied on behalf of Purdue Pharma during the fourth quarter of 2019 based on federal lobbying disclosure forms.

153. The other law firm did file a report for activities relating to access to abuse deterrent pain medication in the third quarter of 2019 and its filing for the fourth quarter suggests that its lobbying concluded on that activity reported in the third quarter. The last bill Purdue paid the firm was in December 2018.

154. While it is impossible to rule out an indirect benefit that may have accrued to Purdue Pharma the records reviewed to this point do not reflect any lobbying being done by Purdue Pharma that would be contrary to the provisions of the Injunction.

155. For example, one retained lobbying firm was engaged on behalf of the Association for Accessible Medicine in connection with labeling of generic drugs which could possibly lead to a promotion of generic opioid products.

156. **I recommend that any agreement with any of the federal government lobbyists or consultants identified herein hereafter be in writing and contain provisions spelling out in detail the Injunction prohibitions on lobbying and the agreement of the lobbyists or consultants to comply with the Injunction as it relates to lobbying. Purdue Pharma agrees with this Recommendation and has committed to implementing it.**

157. The Injunction related only to direct lobbying and does not appear by the letter of the Injunction to cover indirect efforts or to restrict Purdue Pharma from being the beneficiary of indirect efforts.

158. The Injunction requires that all persons engaged in lobbying on behalf of Purdue Pharma certify they have read the Injunction and understand its requirements. The lobbyists underwent a training on the Injunction.

159. **I recommend that all federal lobbyists and consultants be required to furnish quarterly written reports identifying any and all issues and matters they lobbied or engaged in on behalf of Purdue Pharma and its related entities together with a certification by all lobbyists that they have abided by the conditions of the Injunction related to lobbying. Purdue Pharma agrees with this Recommendation and has committed to implementing it.**

160. The Injunction Part II Section D restriction on lobbying also impacts efforts at the state and local government. The state and local efforts are conducted by the State Policy and Government Affairs Group within Purdue Pharma and its related entities under the direction of Purdue Pharma Executive Director, Head of Government Affairs.

161. Purdue Pharma contracts with 22 lobbying firms in 22 states to keep abreast of state legislative activities and a limited amount of state regulatory activities. The firms enter into a master contract that is subsequently extended by an amendment at the expiration of the most recent term. Most of the agreements and extensions were executed before the Injunction so there is no reference to the requirements under the Injunction.

162. Neither the master agreements nor extensions define in any detail the work to be performed under the contract. In later contracts reference is made to Statements of Work and Purchasing Orders; however, no written Statements of Work or Purchase Orders have been created.

163. A review of state disclosure statements from the lobbyist firms retained by Purdue Pharma reflect that lobbying is being done on health care issues generally and opioid issues specifically.

164. For example, the state lobbying firm in Delaware lobbied Senate Bill 34 for Purdue Pharma in 2019. Senate Bill 34 called for the assessment of a fee paid by opioid manufacturers, when and if, the manufacturer exceeds a certain level of production based on morphine milligram equivalents. The collected fee was to be used to pay for prevention services or opioid addiction treatment services. It is unclear from the filing if Purdue Pharma registered for, against or neutral on the bill.

165. Another example of a more general filing was filed by the state lobbying firm working out of the state of Washington. The consulting group disclosed it was paid by Purdue Pharma during the period of September 2019 to December 2019. A time period covered time in which the Injunction came into full force and effect. The work done for Purdue during this period was described as work on Senate Bill 51 involving non opioid directives and coverage of non opioid therapy. It is again unclear if Purdue supported, opposed or remained neutral on the bill.

166. In some cases in the past before the Injunction was issued state lobbyists on behalf of Purdue Pharma registered in opposition to budget bills and substantive bills related to opioid products.

167. For example, the state lobbying firm lobbied and opposed on behalf of Purdue Pharma in the Massachusetts State Legislature SF 1711 and House File 1718 which sought to establish and fund an Opioid Stewardship Fund and HF 3654 that sought to compensate victims of opioid abuse. While the bills were proposed in 2019 those bills might still be considered in a biannual legislative session during 2020. Also, New Jersey disclosure forms filed by the state lobbying firm represented that it is lobbying on behalf of Purdue Pharma in opposing a tax on opioids to fund a prevention and rehabilitation program.

168. The situation in the Massachusetts State Legislature and New Jersey State Legislature may also be at play in the New York State Legislature with S1507A,1507B, and 1507C and S1509A,1509B and 1509C, but it is unclear whether Purdue Pharma registered in opposition to these proposals. The lobbyist filing is confusing. Filings made on behalf of Purdue Pharma suggest that the lobbyist hired by Purdue Pharma was not monitoring the bills; however,

the same filings suggest that Purdue Pharma took a position on the bills but did not disclose what the position was. These bills were enacted into law in April of 2019.

169. **I recommend that all existing contracts and extensions for state lobbyists working on behalf of Purdue Pharma be amended spelling out in detail the specific prohibitions and requirements related to lobbying in the Injunction. The agreements should also include the lobbyist agreement to abide by the requirements and conditions of the Injunction related to lobbying. Purdue Pharma agrees to this recommendation.**

170. **I also recommend that the state lobbyists be required to furnish a quarterly written report identifying any and all issues and matters they lobbied or engaged in for Purdue Pharma, to include the position taken, if any, on any proposed law or regulation. Purdue Pharma agrees to this recommendation.**

171. **I also recommend that the lobbyists provide in writing a certification of compliance with the terms and conditions of the Injunction as it relates to lobbying. Purdue Pharma agrees to this recommendation.**

172. The work of the aforementioned 22 contract lobbying firms is currently supervised by 3 regional directors who handle multiple states and who report to Purdue Pharma Executive Director, Head of Government Affairs.

173. **The range of issues handled at the state level has included active opposition to efforts at the state level to tax opioids and opioid products. Such taxes, I believe, could have an impact on sales and opposition to such taxes could be perceived as promotion of opioid product use. The Company has advised me that it does not agree with this interpretation of the Voluntary Injunction. It believes that lobbying as to the fact of a tax would not constitute "promotion of opioid product use" as promotion is defined in the**

Voluntary Injunction, *see* Section I.O. Moreover, the Company believes that such lobbying is not captured under Sections II D.1.a-c of the Voluntary Injunction which prohibits, among other things, lobbying in favor of health care professionals prescribing opioids. Nonetheless, the Company has agreed with the Monitor that-unless it provides written notice to the Monitor-it will refrain from lobbying against the passage of an opioid tax. Additionally, the Company sought clarification that my interpretation of the Voluntary Injunction does not prohibit lobbying on the issue of how an opioid tax would be structured or administered. I agree with that interpretation, and do not believe that advocacy regarding the structure and administration of opioid taxes would violate the Voluntary Injunction.

174. On other issues directly related to possible promotion Purdue Pharma has not directly opposed legislation adverse to its interests: other similarly situated pharmaceutical companies may have opposed the legislation or rule.

175. Purdue Pharma's Director of Health Policy monitors the various federal relations offices for state governors who have representation in the nation's Capitol.

176. In addition to the 22 state lobbying firms and the state federal relations offices the State Government Affairs Group also subscribes to a daily reporting service with Stateside.

177. Stateside monitors activities at the state level for all 50 states that might impact a pharmaceutical company. In the system at Purdue Pharma certain items have been tabbed, including ADHD prescribing guidelines, drug pricing requirements, price lists, reimportation, Controlled Substances, substance abuse and drug abuse program access, Good Samaritan Laws, Prescription Monitoring Programs (PMP), Take Back Drug Days and drug disposal methods. Issues related to price lists, pricing requirements, reimportation, Controlled Substances, and

PMPs in particular could directly impact opioid and opioid products sales so they need to be closely monitored by the company to assure compliance with the Injunction.

178. All those connected with the state and local lobbying efforts on behalf of Purdue Pharma have purportedly certified they have read the Injunction, understand its requirements and have been trained. I am still in the process of collecting written certifications from all who have lobbied and received the training.

INITIAL COVERED SACKLER PERSONS

179. Under the Injunction the Initial Covered Sackler Persons were not to be actively engaged in the opioid business in the United States or interfere with compliance with the Injunction.

180. A review of the boards, officers and management team of each entity reflects no Initial Covered Sackler Person serving in any such capacity.

181. As monitor I have received signed certifications from all of the named Initial covered Sackler Persons, including, David A. Sackler, Ilene Sackler, Jonathan D. Sackler, Kathe Sackler, Mortimer D.A. Sackler, Richard S. Sackler, Theresa Sackler and the Executor of the Estate of Beverly Sackler certifying that they have not actively engaged in the opioid business in the United States and have taken no action to interfere with Purdue Pharma's compliance with the Injunction.

MISCELLANEOUS

182. Purdue Pharma includes a number of subsidiaries. One such subsidiary is Greenfield Bioventures (Greenfield). Greenfield has acted as an investment fund for emerging technologies.

183. A number of investments have been made by Purdue Pharma and its related entities based on representations from the company that involve a wide variety of technologies. However, as related to these investments, Greenfield entered into a license agreement concerning a rescue medication. Under the Part II, Section A, Paragraph 3 iii of the Injunction Purdue Pharma is not prohibited from activities related to rescue medications.

Wherefore, the undersigned Monitor respectfully submits this Initial 90 Day Report with the recommendations contained in Paragraphs 48, 55, 58, 63, 101, 143, 144, 156, 159, 169, 170, 171 and 173 therein.

Thomas J. Vilsack
Monitor